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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,524	06/27/2000	PETER JOHN BURNE	0769.00140	8239
23552	7590	04/07/2004	EXAMINER	
MERCHANT & GOULD PC			PADMANABHAN, KARTIC	
P.O. BOX 2903			ART UNIT	
MINNEAPOLIS, MN 55402-0903			PAPER NUMBER	
			1641	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,524

Applicant(s)

BURNE ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 154-168, 170-181, 184-198, 200-212, 215 and 216 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 154-168, 170-181, 211 and 212 is/are allowed.
- 6) ☒ Claim(s) 184-198, 200-210, 215 and 216 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/27/00 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/04 has been entered.

Response to Amendment

2. The declaration under 37 CFR 1.132 filed 2/24/04 is sufficient to overcome the rejection of claims 154-168, 170-181, and 211-212 based upon 35 USC 103 over Bergman, Ehrenkranz, May, and Foster.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 184-198, 200-210, and 215-216 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergman (US Pat. 5,501,955) in view of Ehrenkranz (WO 96/27129), May et al. (US Pat. 5,622,871), and Foster et al. (US Pat. 4,444,879).

Bergman teaches a method for detecting the presence of autoantibodies in biological fluids, such as serum (col. 3, line 67) by a) providing an antigen specific for autoantibody such as thyroid peroxidase; b) providing a substrate having an immobilized antibody specific for the antigen; c) contacting the antigen with a body fluid sample to allow binding of the complex; d) allowing the mixture to flow into the test tube to contact the immobilized monoclonal antibody; e) providing labeling means such as labeled non-immobilized monoclonal antibody to allow binding to the complex, which is an indication of the presence of autoantibody in a sample of body fluid (fig 1 and cols. 3-4). The reference also teaches various formats for the detection of autoantibodies. The reference states that sandwich complexes with a specification of suitable properties for detection of certain autoantibodies can be tailored when both the immobilized and labeled antibodies are monoclonal (col. 4, lines 50-55). The reference also teaches three different competitive situations involving analyte-antibody analysis. In Fig 1, analyte competes

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for the same binding site as the immobilized antibody. In Fig 2, analyte competes for the same binding site as the labeled antibody. In Fig 3, analyte competes for the same binding site as both labeled and immobilized antibodies. The reference does not teach the use of first and second immobilized antibodies that bind to distinct binding sites on an antigen or of a test strip as the substrate.

Ehrenkranz teaches a TSH immunoassay, wherein the assay comprises a labeled antibody in mobile phase, and a second antibody in a stationary phase. The antibodies are chosen such that they each bind to different epitopes on TSH, such that both antibodies may bind to TSH to form a sandwich (abstract). The assay may be conducted on whole blood, serum, or plasma (page 3). The assay is conducted in a test strip format.

May et al. teach a test strip format in which assays involving specific binding or immunoassays may be formatted in a test strip to provide convenience for home or clinical use. A sample may be applied to a portion of the test strip and allowed to permeate through the test material. A control zone may be designed to detect unrelated signal to the user that the device is working. The sample progresses to a detection zone where a specific binding partner for the sample analyte is immobilized. Analyte concentration may be determined by a labeled reagent that can be incorporated within the test strip or applied thereto (col. 1, lines 35-60). Direct labels such as metallic sols (e.g. gold) can be used for an analytical result (col. 5, lines 29-32). The substrates involved in the test strip are porous membranes such as nitrocellulose (col. 7, lines 5-10).

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Foster et al. teach a kit in which an immunoassay of the invention is incorporated. The kit contains a substrate, buffers, and other reagents, controls, instructions, containers, and any other pertinent components of the immunoassay of the invention (col. 15, lines 12-34).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Bergman et al. by providing a multivalent antigen such as TSH and antibodies specific for the pertinent epitopes as taught by Ehrenkranz because this assay method provides for a selective, sensitive, and rapid immunoassay. It would have also been obvious to conduct the method of Bergman in a test strip format as taught by Ehrenkranz and May et al. because the use of a test strip provides for rapid analytical results with a great degree of convenience and little required involvement from the user. In addition, although the references only specifically teach the labeling of antibodies and not antigens to monitor binding of the antigen to autoantibodies, one of skill in the art would have known that the labeling of antigens would have achieved the same end result, and such labeling is deemed to be routine optimization in the art. Finally, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the modified method of Bergman, Ehrenkranz, and May et al. by incorporating a kit containing all the necessary reagents and supplies, as taught by Foster et al. because kits are well known in the art and are widely recognized for their advantages of economy and convenience.

Allowable Subject Matter

7. In view of applicant's amendments and arguments, and submission of declaration under 37 CFR 1.132, claims 154-168, 170-181, and 211-212 are allowed.

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8. The following is a statement of reasons for the indication of allowable subject matter: the closest prior art of record fail to disclose or teach methods for screening a sample for first and second autoantibodies to at least one antigen, comprising all the steps and components recited in the presently allowed claims.

Response to Arguments

9. Applicant's arguments filed 2/24/04 have been fully considered but they are not persuasive to overcome the rejection of the claims drawn to a kit.

10. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

11. Applicant's arguments with respect to the kit claims closely parallel those arguments in favor of the patentability of the method claims. However, the functional limitations incorporated in the claims drawn to a kit are not given patentable weight, as they would be (and have been) in the method claims. As such, as long as all the components of the kit are taught, the way in which those components function or their intended use is immaterial to the issue of the patentability of the kit. As such, the examiner maintains that all the components of the kit claims are taught by the references (See 35 USC 103 rejection above), and the rejection is therefore maintained over these claims.

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Conclusion

Claims 154-168, 170-181, and 211-212 are allowed. Claims 184-198, 200-210, and 215-216 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
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09/05/04